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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/510,655

11/30/2004

Hans Groenlund

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EXAMINER

ROONEY, NORA MAUREEN

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,655	Applicant(s) GROENLUND ET AL.	
	Examiner NORA M. ROONEY	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-14 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1008/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-6 and 9-14 are pending.
2. Applicant's election with traverse of Group I, claims 1-6 and 9-10 in the reply filed on 11/27/2007 is acknowledged. The traversal is on the ground(s) that "Applicants respectfully request reconsideration of the restriction requirement on the grounds that examination of the entirety of the claims would not constitute an undue burden. Public policy dictates that if the search and examination of all the claims in a patent application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to more than one independent invention. In this case, claims 11-14 depend from and thus require all the particulars of claim 1. Accordingly, the search required for the elected microparticle of Group I overlaps with, and indeed is central to, the search required for the non-elected methods of Groups II and III. Thus, Applicants submit that it would not be an undue burden for the Examiner to consider claims 11-14 together in the present application. Accordingly, Applicants respectfully request that the Examiner reconsider the Restriction Requirement and specifically reconsider examining non-elected claims 11-14 with the elected invention of Group I."

This is not found persuasive because public policy and search burden are not the standard for establishing that the claims lack unity of invention. As set forth in the Office Action mailed on 11/13/2007, the claims lack unity of invention because they do not contribute a special technical feature over the prior art of King et al. and Nordvall et al. Further, the claims are

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directed to two distinct inventions which would be a burden to search given that the scope of prior art references may not read on all of the inventions.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 11-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 11/27/2007.

4. Claims 1-6 and 9-10 are currently under examination as they read on a microparticle comprising a bead and a plant pollen allergen.

5. Applicant's IDS document filed on 10/08/2004 is acknowledged.

Claim Objections

6. Claims 9-10 are objected to because of the following informalities: Claim 9 and Claim 10 which depends from claim 9 are dependent upon cancelled claims 7-8. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-6 and 9-10 *are* rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for : a microparticle consisting essentially of CBP and Phl p 5b, does not provide reasonable enablement for : a microparticle comprising a) **a bead consisting essentially of a three dimensionally cross-linked carbohydrate** and b) **an allergen** which is covalently bound to the bead, wherein c) **the allergen is derived from plant pollen** of claim 1; wherein **the allergen is derived from grass pollen** of claim 3; wherein **the allergen is derived from timothy grass pollen** of claim 4; **A medicament** for the treatment of the immune system comprising microparticles according to any one of claims 1-8 of claim 9; and which is formulated characterized in that it is prepared for parenteral application of claim 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the

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amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification does not adequately disclose a bead made of "a three dimensionally cross-linked carbohydrate." The specification only discloses cyanogen bromide-activated spherical Sepharose particles (CBP) for use in the claimed invention.

The specification also does not adequately disclose any "allergen" for use in the claimed invention. The term "allergen" encompasses non-peptide molecules, such as metals, which would not covalently bind to a three dimensionally cross-linked carbohydrate. The specification has only disclosed Phl 5 5b for use in the claimed invention to be covalently bound to CBP. Because of the unpredictability of determining which allergens would covalently bind the bead and because the specification had not provided guidance or adequately disclosed the genus of allergens that can be used in the claimed invention, one of ordinary skill in the art at the time of invention would not be able to practice the invention commensurate in scope with the claims.

The specification fails to provide sufficient enablement for a person of skill in the art to use a medicament "for treatment of the immune system" because the term "treatment of the immune system" encompasses positive and negative responses. The same molecule cannot be used to enhance and inhibit the same response. The term also applies to all responses. There is a significant lack of direction and guidance as to how the medicament "treats the immune system."

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Therefore, an undue amount of experimentation is required to enable one of skill in the art to practice the claimed invention. A myriad of agents are encompassed by the claims. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of microparticles, medicaments and immune system responses broadly encompassed by the claims.

Also at issue is whether the microparticle could be used in a medicament to treat the immune system. In view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the medicament as claimed, absence of working examples providing evidence which is reasonably predictive and commensurate in scope with the claims that the claimed medicament is effective for in vivo use to treat the immune system, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed vaccine with a reasonable expectation of success.

Substantiating evidence may be in the form of animal tests, which constitute recognized screening procedures with clear relevance to efficacy in humans. See *Ex parte Krepelka*, 231 USPQ 746 (Board of Patent Appeals and Interferences 1986) and cases cited therein. *Ex parte Maas*, 9 USPQ2d 1746.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working

examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

9. Claims 1-6 and 9-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of: nucleic a microparticle consisting essentially of CBP and Phl p 5b.

Applicant is not in possession of: a microparticle comprising a) **a bead consisting essentially of a three dimensionally cross-linked carbohydrate** and b) **an allergen** which is covalently bound to the bead, wherein c) **the allergen is derived from plant pollen** of claim 1; wherein **the allergen is derived from grass pollen** of claim 3; wherein **the allergen is derived from timothy grass pollen** of claim 4; **A medicament** for the treatment of the immune system comprising microparticles according to any one of claims 1-8 of claim 9; and which is formulated characterized in that it is prepared for parenteral application of claim 10.

Applicant has disclosed only a microparticle consisting essentially of CBP and Phl p 5b; therefore, the skilled artisan cannot envision all the contemplated microparticle and medicament possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method.

Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-6 and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Nordvall et al. (PTO-892 mailed on 11/13/2007).

Nordvall et al. teaches a microparticle comprising a) a bead consisting essentially of a three dimensionally cross-linked carbohydrate (Sephacrose beaded agarose) and b) an allergen (timothy pollen allergen) which is covalently bound to the bead, wherein c) the allergen is derived from plant pollen (timohty pollen allergen); wherein the allergen is derived from grass pollen; and wherein the allergen is derived from timothy grass pollen (In particular, whole document, page 577, right column, first whole paragraph).

Claims 5 and 6 are included in this rejection because the office does not have a laboratory

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to test the reference composition. It is applicant's burden to show that the reference microparticle size range is not 0.1 μm to 10 μm . See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Claims 9-10 are included in this rejection because the medicament reads on microparticles without a carrier.

The reference teachings anticipate the claimed invention.

12. Claims 1-3, 5-6 and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by King et al. (PTO-892 mailed on 11/13/2007).

King et al. teaches a microparticle comprising a) a bead (Sepaharose beaded agarose) consisting essentially of a three dimensionally cross-linked carbohydrate and b) an allergen (*Dactylis plomerulata* grass pollen) which is covalently bound to the bead, wherein c) the allergen is derived from plant pollen (In particular, abstract, whole document, page 340-341); wherein the allergen is derived from grass pollen; a medicament for the treatment of the immune system comprising microparticles (allergen-bead complex suspended in .1M borate and NaCl) (In particular, page 341, first full paragraph); and which is formulated characterized in that it is

prepared for parenteral application (allergen-bead complex suspended in .1M borate and NaCl)
(In particular, page 341, first full paragraph)

Claims 5 and 6 are included in this rejection because the office does not have a laboratory to test the reference composition. It is applicant's burden to show that the reference microparticle size range is not 0.1 μm to 10 μm . See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

The reference teachings anticipate the claimed invention.

13. Claims 1-2, 5-6 and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by van Toorenenbergen et al. (PTO-892; Reference U).

van Toorenenbergen et al. teaches a microparticle comprising a) a bead consisting essentially of a three dimensionally cross-linked carbohydrate (agarose beads) and b) an allergen (tomato pollen) which is covalently bound to the bead, wherein c) the allergen is derived from plant pollen (tomato pollen); a medicament for the treatment of the immune system comprising microparticles; and which is formulated characterized in that it is prepared for parenteral application (In particular, abstract, page 248 'IgE antibody measurements section').

Claims 5 and 6 are included in this rejection because the office does not have a laboratory

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to test the reference composition. It is applicant's burden to show that the reference microparticle size range is not 0.1 μm to 10 μm . See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

The reference teachings anticipate the claimed invention.

14. Claims 1-6 and 9-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Gronlund et al. (PTO-892; Reference W).

Gronlund et al. teaches a 2.1 μm microparticle comprising a) a carbohydrate bead consisting essentially of agarose and b) rPhl p 5b allergen which is covalently bound to the bead, wherein c) the allergen is derived from timothy grass pollen and a medicament for the treatment of the immune system comprising microparticles which is formulated characterized in that it is prepared for parenteral application (In particular, abstract, whole document).

The reference teachings anticipate the claimed invention.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1 and 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Toorenbergen et al. (PTO-892, Reference U) in view of Nordvall et al. (IDS filed on 11/13/2007).

van Toorenbergen et al. and Nordvall et al. have been discussed supra.

The claimed invention differs from the prior art in the recitation of "wherein the allergen is derived from grass pollen" in claim 3 and "wherein the allergen is derived from timothy grass pollen" of claim 4.

It would have been obvious to one of ordinary skill in the art at the time of invention to use the timothy grass pollen allergen of Nordvall et al. in the microparticle of van Toorenbergen et al. because van Toorenbergen et al. teaches that there is a high incidence of occupational allergy in horticulture and that the microparticles comprising pollen allergens covalently bound to agarose beads can be used to diagnose allergy to pollen and fruit (In particular, abstract, whole document).

From the reference teachings, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the

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invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

17. Claims 1 and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Toorenbergen et al. (PTO-892, Reference U) , Nordvall et al. (IDS filed on 11/13/2007) or King et al. (IDS filed on 11/13/2007); each in view of Johansen et al. (PTO-892; Reference V).

Toorenbergen et al., Nordvall et al., King et al., and Gronlund et al. have been discussed *supra*.

The claimed invention differs from the prior art in the recitation of "wherein the particle size ranges from .1 μ m to 10 μ m" in claim 5 and wherein the particle size ranges from .5 μ m to 5 μ m" in claim 6.

Johansen et al. teaches all of the important features of microspheres for antigen delivery in parenteral administration, including the importance of microsphere size (In particular, whole document). The reference specifically teaches that microsphere sizes of less than 10 μ m allow for enhanced stimulation of primary and MHC-restricted responses (In particular, Table 2 on page 132) and smaller-sized microspheres (e.g. 1-5 μ m elicit faster and more efficacious responses than larger particles (in particular, page 139, first full paragraph).

It would have been obvious to one of ordinary skill in the art at the time of invention to use microparticles with size ranges between .1 to 10 μm as taught by Johansen et al. in the microparticles taught by Toorenbergen et al., Nordvall et al., King et al., and Gronlund et al. because Johansen et al. teaches that microparticles under 10 μm enhance stimulation of primary and MHC-restricted responses and elicit their effect more quickly and effectively than larger particles.

From the reference teachings, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 14, 2008

Nora M. Rooney, M.S., J.D.

Patent Examiner

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Primary Examiner,
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